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REMARKS

The last Office Action dated 3/29/04 has been carefully considered. It is believed that the above amendments to the claims are fully responsive to overcome the Examiner's objections to claims, 73 and 85, and rejections on the basis of 35 U.S.C. §112 second paragraphs to claims 67, 74, 79. It is believed that the new claims submitted herein are patentable, notwithstanding the examiner's prior rejections under 35 U.S.C. §103 as applied to prior claims 67-84. As the new claims are constructed largely to overcome the examiners objections and rejections under 35 U.S. C §112, but are directed at essentially the same elements and limitations as the earlier presented claims, the Applicant does not believe a new a new search is required.

Accordingly, the Applicant requests that the finality of the prior office action be withdrawn and that reconsideration be given to the new claims in light of the arguments made herein.

The Applicant's new claims are directed to tubing having a novel composition, consistent with the restriction requirement made in the office action of March 13, 2003. The composition comprises three components; what are substantially a homopolymer, a block copolymer, and nanocomposite particles. At least one of the block segments in the block copolymer is formed from either the same monomer as the homopolymer, or a monomer having the same reactive end groups as those that form the homopolymer. Dependent claims 89 – 106 contain limitations to the type and identity of the homopolymer, block copolymer, the proportion of nanocomposite filler, dimensions of the tubing, the mechanical properties of the tubing, and/or the method of mixing the components during fabrication of the tubing. The Applicant has discovered that the blends of homopolymer, block copolymers and nanoparticles offer previously unidentified benefits in the manufacture and use of tubing for medical catheters. Specifically, at least two of the following three benefits are achieved, depending on the specific composition:

1. Achieve an intermediate elastic modulus, between that of the components of the polymer blend, yet without a loss of toughness, and in some instances increased

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toughness (for specific compositions)

2. Improvement in a lower propensity to retain dirt
3. Improved dimensional stability in the process of extruding narrow diameter, thin wall tubing

All of the new claims are to tubing that is formed from novel polymer blend compositions leading to one or more of these improved properties.

It is noted that the majority of the claims previously presented claims (67, 68, 71-80, 83-85) were rejected under 35 U.S.C. § 103 as being unpatentable over Bagaoisan (U.S. Pat. No. 6,270,477) in view of Beall (U.S. Pat. No. 5,578,672) while the remainder of the claims (70, 71, 81, 82) were rejected over Bagaoisan (U.S. Pat. No. 6,270,477) in view of Beall (U.S. Pat. No. 5,578,672)) and in further review of Tse (U.S. Patent No. 4,717,618). The examiner is requested to reconsider the propriety of the 35 U.S.C. §103 rejections in presenting a prima facie argument for obviousness with respect to the new claims as:

1. Bagaoisan and Beall do not provide a motivation to combine, and are therefore improper as a basis for a 103 rejection, see *Ex parte Levengood*, 28 USPQ 2d 1300, 1301-02 (B.P.A.I. 1993), holding that "Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done."

2. Bagaoisan and Beall are not properly combined as they teach away from each other

3. Bagaoisan, Beall and Tse are not properly combined as they teach away from each other

4. Assuming, for the sake of argument, that the examiner has made a sufficient case for non-obviousness to establish a prima facie case of obviousness, the weight of the evidence in the Applicant's original specification overwhelmingly supports a finding

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of non-obviousness. Specifically, the Applicant has discovered new result effective variable, which produce results that are themselves unexpected in light of the prior art.

Therefore, in light of the more detailed arguments and evidence that follows, it is respectfully submitted that the new claims 86-108 clearly and patentably distinguish over the prior art, since it is believed that the construction defined in these claims differs essentially and in an unobvious, highly advantageous manner from the constructions disclosed in the references. Applicant believes that combining the references discussed above, and those asserted in earlier office actions, would not lead to the claimed invention, in that the present invention does not merely employ the known substitution of equivalents but rather employs a new, non-obvious combination to accomplish the objectives set out in the present application.

1. Bagaoisan and Beall do not provide a motivation to combine, and are therefore improper as a basis for a 103 rejection. Thus, the examiner has not established a prima facie case under 35 U.S.C. §103.

It is further respectfully submitted that the combined teachings of the references applied by the Examiner fail to disclose or even suggest the subject matter of the new claims. Specifically, the Applicant believes that the Examiner's argument regarding the motivating force to combine Beall is based on a generic teaching of improved properties, yet ignores Beall's suggestion and teaching that properties discovered in the Applicant's invention are mutually exclusive. As such, the rejection violates the well-established principle that a Genus does not anticipate a Species.

That a prior art reference could be modified to form the claimed structure does not supply a suggestion to do so. "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." *In re Laskowski*, 871 F.2d 115, 10 USPQ2d 1397 (Fed. Cir. 1989).

Neither reference teaches the combination claimed by the Applicant, which is reinforcement of the blend of Nylon and PEBAX taught by Beall, with the

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nanocomposite particles taught by Bagaoisan. Bagaoisan teaches combining specific block copolymer disclosed by the Applicant (i.e. PEBAX) with some of the same homopolymers disclosed by the Applicant (various Nylon homopolymers). Bagaoisan's purpose for formulating such blends is to reduce the rigidity or modulus of the Nylon homopolymer, so as to form catheter tubing having a more flexible, that is less rigid tip at one end, and is more rigid at the opposite end (see column 1, line 65). It further states in column 5, line 51 that:

"Where increased flexibility of the distal end 14 of catheter 10 is desired, PEBAX (TM) may be used in place of PTFE along a selected portion of distal end 14, such as the distal most 15-20 cm of end 14."

Bagaoisan goes on to state that blends of PEBAX with other polymers to modify the flexibility of other parts of the catheter, for example in column 9, line 16:

"Moreover, any of a variety of different polymeric materials known by those of skill in the art to be suitable for catheter body manufacture may be used to form tubular body 16. For example, tubular body 16 may be formed out of PEBAX (TM), blends of PEBAX (TM), and nylons, polyetheretherketone (PEEK), polyethylenes, and Hytrel (TM), and the like. Different materials might also be combined or blended to select for desirable flexibility properties."

In summary then, Bagaoisan's suggestion to use "blends of PEBAX and Nylon" is motivated by the ability to fabricate different parts of the catheter having a flexibility intermediate between that of the stiffer homopolymer, nylon, and the softer or lower modulus PEBAX copolymers. In fact, in FIG. 1 of Tse discloses that polyether-amide block copolymers, such as PEBAX, offer a range of hardness value that extends below that of polyamides, i.e. Nylons.

Beall teaches a method and compositions for forming nanocomposites that include mixing nanocomposite particles with among other polymers, polyamides. Beall teaches that the combination of nanoparticles may be used to improve, that is increase, the following physical properties of a polymer:

1. "elasticity and temperature characteristics" (column 1, line 43)

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2. "glass transition temperature and high temperature resistance" (column 1, line 43-44)
3. "impart greater mechanical reinforcement and a higher glass transition temperature" (column 6, line 34-35)
4. "lower permeability"(column 6, line 37)
5. "Substantially enhanced barrier properties and heat resistance (deflection temperature under load, DTUL) are imparted by platelet particle concentrations greater than about 2.5%." (column 15, line 9-10)
6. "significantly enhances modulus, dimensional stability, and wet strength" (column 15, 19-20)

Of greater significance, Beall admits of certain limitations indicating that certain properties are generally obtained in the alternative, at column 21, line 19-26:

"The effect of adding into a matrix polymer the nanoscale particulate dispersed platelet particles, derived from the intercalates formed in accordance with the present invention, typically is an increase in tensile modulus and ultimate tensile strength or an increase in ultimate impact resistance or glass transition temperature (Tg).

As Beall speaks of increasing the tensile modulus (and strength) in the alternative of increasing the ultimate impact resistance, it would not be expected that nanocomposite particles taught by Beall could be used to achieve both an increase in modulus and an increase in toughness, or increased modulus without a loss in toughness, toughness being roughly related to impact strength, or the product of tensile strength and elongation to break as disclosed by the Applicant.

The Applicant's specification teaches that particular blend combinations result in a modulus intermediate between the components without a decrease in elongation or toughness as measured by the product of elongation and tensile strength. These unexpected benefits are specifically reflected in new dependent claims 99-102. In reviewing the new claims, the examiner is urged to consider all claim limitations, in

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particular the criteria set forth in *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216, 36 USPQ2d 1225, 1228 (Fed. Cir. 1995)

"While the measurement of a physical property may not of itself impart patentability to otherwise unpatentable claims, when the measured property serves to point up the distinction from the prior art, or advantages over the prior art, that property is relevant to patentability, and its numerical parameters can not only add precision to the claims but also may be considered, along with all of the evidence, in determination of patentability."

2. Bagaoisan and Beall are further improperly combined as they teach away from each other, and thus do not support obviousness rejections.

As set forth by *McGinley v. Franklin Sports Inc.*, 60 USPQ 2d 1001, 1010 (Fed. Cir. 2001), stating:

"We have noted elsewhere, as a "useful general rule," that references that teach away cannot serve to create a prima facie case of obviousness."

See also *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 45 USPQ 2d 1977, 1984 (Fed. Cir. 1998) and *In re Gurley*, 27 F.3d 551, 553, 31 USPQ 2d 1130 (Fed. Cir. 1994).

"If references taken in combination would produce a "seemingly inoperative device," we have held that such references teach away from the combination and thus cannot serve as predicates for a prima facie case of obviousness.

Bagaoisan, as previously stated, teaches softening (i.e. achieving a lower elastic modulus) polymers by substituting or blending PEBAX with harder materials (those having a higher elastic modulus). Beall teaches reinforcement of polymer to increase, among other properties, the elastic modulus.

Adding PEBAX, as taught by Bagaoisan, to the compositions taught by Beall would have the effect of lowering the modulus, whereas Beall seeks the opposite property, increased modulus.

Adding the nanocomposite particle of Beall to the PEBAX and Nylon blends of Bagaoisan would have the undesirable effect of increasing the modulus when

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Bagaoisan's objective is to decrease the modulus below that of the harder homopolymer (Nylon)

3. Bagaoisan, Beall and Tse are not properly combined as they teach away from each other. The examiner has not established a *Prima facie* case under 35 U.S.C. §103 with respect to the Beall and Bagaoisan references, in view of Tse.

It is noted that original Claims 69, 70, 81 and 82 were rejected as unpatentable over Bagaoisan in view of Beall and in view of Tse. Bagaoisan and Tsai do not teach the combination claimed in the instant invention, and in fact, both teach away from Beall, which suggests using Nanoparticles to harden or increase the modulus of a polymer, suggesting the use of Nylon block copolymers to reduce the hardness, modulus of otherwise harder or more brittle polymers. Please refer to Figure 1 of Tse, which shows the ranges of hardness available with polyamides (nylons) and polyether-amide block copolymers (which include PEBAX) as being of lower hardness, which is lower modulus, suggesting at best their utility to reduce the hardness of another material.

Tse is not properly combined with Beall for the same reason as Bagaoisan. Tse seeks to reduce the hard and brittle nature of EVOH copolymers by adding softer and more extensible PEBA (such as PEBAX, at column 7, lines 27-30). Thus adding nanocomposite particles as taught by Beall would not be pursued by one of ordinary skill in the art, as it produces the opposite result, increasing the elastic modulus of any such blend, making it harder and more like EVOH. Specifically, Tse teaches away from the combination claimed as, at column 4, lines 23-26:

"This PEBA is generally desirable because its generally soft "hardness" is conducive to a softening modification of the hard and brittle EVOH when blended with the EVOH.

As well as column 6, lines 24-31:

The basic concept derived is that the PEBA functions to lend its softness, flexibility, and toughness to the otherwise relatively brittle and fragile EVOH, thereby modifying its properties to yield a film having improved extensibility and toughness."

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In an earlier office action, dated March 13, 2003, the Examiner rejected original claim 19, which containing a limitation to dirt retention properties, citing Havens (U.S. Pat. no. 4,889,521). However, the examiner has mischaracterized this references, as it does not teach that all types of PEBAX improves anti-static properties, which might be responsible for a reduction in dirt attraction or retention, but rather teaches that for useful grades of PEBAX where high moisture stability is important, anti-static additives must be added to PEBAX to achieve anti-static properties. Hence, Haven's should be considered as teaching away from the applicants invention, as one seeking anti-static properties to avoid dirt retention would not add a polymer that required an anti-static additive to achieve such properties.

Thus, the Applicants discovery of low dirt retention with PEBAX 2533 and 7233 would not be expected, as these grades are comparable to those described in Havens, which require incorporating an anti-static additive into the material. Havens also notes that the while another grade 4011 has an anti-static nature, the 33 series used by the Applicant does not:

"The brochure states that Pebax 4011 by itself is antistatic in nature because it is extremely hydrophilic, as it will absorb 120% of its weight in water when allowed to soak for 24 hours. This material is so hydrophilic that it would be inappropriate for packaging electronic devices, as so much moisture from the atmosphere would be attracted that as the water released it would corrode the packaged device. Thus, it is herein defined that by the terms "polyether block amide copolymer", "polyamide-polyether copolymer", and "PAEPC", which are used interchangeably, it is not intended to include the extremely hydrophilic Pebax.RTM. 4011 or any other polyether block amide copolymer that is as hydrophilic as, or substantially as hydrophilic as, Pebax.RTM. 4011. It is intended to include polyether block amide copolymer having a degree of hydrophilicity suitable for packaging electronic devices. While it is not intended to be bound to any theory, it is believed that the extremely hydrophilic characteristic of Pebax 4011 is due to the EP component of the Pebax 4011 copolymer forming a helix with the oxygens inside, which tends to hold moisture inside the helix. Pebax 4011 is about 50% by weight EP and 50% by weight PA. The brochure also states the natural Pebax grades of the Pebax--33 series have a surface resistivity of 10.sup.10 ohms.multidot.cm. The brochure also describes making the Pebax grades of the Pebax--33 series of copolymers semi-conductive by adding carbon black thereto. It is noted here that the addition of carbon black to polymers to make them semi-

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conductive is old technology and well known to those skilled in the art of antistatic and conductive polymeric chemistry. "

Further, current ATO product literature, attached hereto, also states ,that only certain grades of PEBAX have inherent anti-static properties:

"Antistatic agents : Pebax® MH 1657/MV 1074 polymers naturally disperse electrostatic charges, and as such can be added to a large number of thermoplastic matrices (ABS, polystyrene, POM, PVC, PMMA, polycarbonate, etc.) to impart permanent antistatic properties whatever ambient relative moisture or surface friction they may be subjected to. ... "These Pebax® antistatic compounds are suitable for countless applications in office and electronic equipment (photocopier components, printer components, etc.) as well as in technical packaging."

Further as Beall teaches using nanoparticles to decrease moisture absorption, which may be related, through the enhancement of anti-static properties, to the low dirt retention discovered by the Applicant, one would not be motivated to follow the alleged teaching of Havens to combine PEBAX with nanoparticles, as the nanoparticles would reduce the moisture absorption.

Thus, following *Bausach & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 230 USPQ 416 (Fed. Cir. 1986) stating that

"as a reference should be considered as a whole, and portions arguing against or teaching away from the claimed invention must be considered".

The Applicant respectfully submits that Havens does not provides a motivation to add non-inherently anti-static grades of PEBAX to obtain tubing with reduced dirt retention, in part because they do not inherently impart such properties, ergo the improved properties obtained clearly do not arise from anti-static effects imparted by the PEBAX.

4. Assuming, for the sake of argument, that the examiner has made a sufficient case for non-obviousness, the weight of the evidence in the Applicant's original specification overwhelmingly rebuts such arguments.

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A. Examiners assertion that the Applicant has merely optimized within a known range is without basis, as the prior art does not teach the variable or the property it improves.

With respect to original claim 79, the examiner exerts that *In re Boesch* applies in that discovering an optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results" (page 11, paragraph 13. The Applicant contends that *In Re Boesch* is not applicable, as discovering the optimum value of a result effective variable involves only routine skill in the art in the absence of unexpected results.

The prior art does not teach the result effective variable, to wit; that nanocomposite particles should be added to a blend of a homopolymer and a block copolymer intended to reduce the modulus of the homopolymer), or the result that should be expected to be optimized (toughness contributed by one component in the blend is sustained, while modulus is reduced, or improvement in dirt retention). Further, in rejecting the Applicants earlier argument with respect to originally submitted claims 74 and 79, the examiner states (p. 2, paragraph 16 of the last office action) that the Applicant has not met the burden on the Applicant that these results are in fact unexpected and unobvious and of both statistical and practical significance, citing *Ex parte Gelles*.

B. Assuming the Examiner's assertion is proper, the Applicant has already met any alleged burden of showing that the results are unexpected

Ex parte Gelles is only applicable when the examiner has indeed made a *Prima facie* case of obviousness on the basis of the prior art disclosing a result effective variable. Further, even if the prior art disclosed nanoparticles as being a result effective variable for the specific properties discovered by the Applicant, *Ex parte Gelles* is not applicable under *In re Soni*, 34 USPQ 2d 1684, 1687 (Fed. Cir. 1995). *In Re Soni* established that the original specification can be sufficient to show unexpected results, stating

Merely improvement in properties does not always suffice to show unexpected results. In our view, however, when an applicant demonstrates substantially improved results, as Soni did here, and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary. "

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"Consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results."

The court further stated that:

"The principle applies most often to the less predictable fields, such as chemistry, where minor changes in a product or process may yield substantially different results."

The Applicant has specifically met the criteria set forth in *In Re Soni*, by 1) described unexpected benefits in the specification, and 2) making a comparison with the closest prior art. The Applicant states in his specification that the benefits are:

"This invention is directed primarily toward those medical applications such as catheters and balloons requiring improvements in many mechanical and other properties such as the balance between stiffness and flexibility, dimensional stability, and less tacky surfaces to decrease the tendency for the material to pick up dirt and other contaminants, and lubricity for ease of travel through the tube."

The Applicant states in paragraph 52, among other places, that the results are indeed unexpected:

"The present invention provides a means for combining of nanocomposite reinforced polymers with pure Nylon based materials for the purpose of yielding mechanical and other property balances that are new and unexpected while also being uniquely predictable."

In addition, paragraph 69:

"[0069] The Nylon 11 nanocomposite which was blended with the Pebax 7233 produced a resultant polymer having intermediate stiffness. However, it was less ductile than either of the two individual blend components. It was determined that the 50/50 blend was inferior to the blend of Nylon 12 and Pebax 7233. This was a genuinely unexpected result".

And paragraph 77:

"It has also been determined that some copolymers provide new and unexpected values for mechanical properties such as toughness"

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In summary, the Applicant has discovered properties that are substantially improved over the prior art, as the prior art is silent on the properties of toughness, dirt retention and dimensional stability, that improved by the novel claimed tubing as defined by its composition. Further the closest prior art has been compared in the specification via tabular data showing various physical properties of tubing fabricated without either of the particular optimum homopolymer, PEBAX, or provides data for the nanocomposite reinforced homopolymer only. For examples, see Tables 4-8, wherein ++, as indicated by the legend in Fig. 2, signifies much improved properties for various nanocomposite compositions.

As for all of the previously proposed combinations of references cited by the examiner in past office actions, it is respectfully submitted that since none of the references in the combination teaches the distinctive features of Applicant's invention as defined now in the new claims 86-108, any hypothetical construction produced by this combination would not lead to Applicant's invention.

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In view of these considerations, it is respectfully submitted that the rejection of the original claims should be considered as no longer tenable with respect to the new claims 86-108 and should be withdrawn. The new claims 86-108 should be considered as patentably distinguishing over the art and should be allowed. However, to the extent that the Examiner disagrees with the Applicant, the Applicant requests the entry of the amended claims.

A petition is hereby made under 37 CFR 1.136 for a one-month extension of time to respond to the final office action, with the fee being paid by the attached credit card form.

Should the Examiner consider necessary or desirable any formal changes anywhere in the specification, claims and/or drawing, then it is respectfully asked that such changes be made by Examiner's Amendment, if the Examiner feels this would facilitate passage of the case to issuance. Alternatively should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, he is invited to telephone the undersigned.

Respectfully submitted:

By:  on 6/29/2004

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